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Item 8: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market SignaDRESS Hydrocolloid Dressing.

SignaDRESS is a hydrocolloid dressing consisting of an inner (wound contact) layer of hydrocolloids contained within an adhesive polymer matrix and an outer layer of polyurethane backing film. The dressing also has a product identification mark (ConvaTec registered tear drop trademark) and a visible (SignaDRESS) change indicator guide printed on the film backing.

The dressing adheres to dry and moist tissue and provides a barrier against bacteria and other external contamination as long as the dressing is intact. SignaDRESS is featured with a delivery system that allows clinicians to apply the dressing without touching the adhesive mass. This feature is especially beneficial when gloves are worn to apply the dressing; it minimizes the chance of the gloves sticking to the adhesive mass. A visible change indicator printed on the polyurethane backing film helps simplify wound dressing management for the care giver.

SignaDRESS is intended for chronic wounds-pressure ulcers (Stage I-IV) and leg ulcers. SignaDRESS is also indicated for use on acute wounds-surgical wounds (post-operative wounds and donor sites), traumatic wounds (minor abrasions and lacerations), burns (first and second degree), and dermatological excisions.

SignaDRESS Hydrocolloid Dressing is contraindicated for use on individuals with known sensitivity to the dressing or its components.

SignaDRESS is substantially equivalent to Coloplast's Comfeel Plus Ulcer Dressing. Both dressings have essentially the same intended uses, contraindications, precautions, and observations. SignaDRESS is similar in construction and design to Comfeel Plus Ulcer Dressing whereby both dressings consist of a polyurethane backing film printed with a change indicator or measurement grid. Also both dressings are comprised of a hydrocolloid adhesive wound contact layer. Both devices are regulated by the same classification panel. Further classification information is located in Item 1d of this application.

Comparative bench testing was conducted to determine the performance of SignaDRESS and Comfeel Plus Ulcer Dressing. The dressings performed essentially the same with regards to coefficient of friction, absorbency, peel adhesion, and bacterial barrier testing. A summary of the tests and corresponding reports are included in section 5a of this application.

SignaDRESS Hydrocolloid Dressing has been subjected to biocompatibility testing utilizing the ISO 10993 Part I "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995). The results of this testing demonstrate that SignaDRESS is considered to be non-toxic, non-cytotoxic, and a negligible irritant. Test reports appear in Item 5 of this application.